

Anticipation under Section 102 of the Patent Act requires that a prior art reference disclose every claim element of the claimed invention. See, e.g., Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1574 (Fed. Cir. 1986). While other references may be used to interpret an allegedly anticipating reference, anticipation must be found in a single reference. See, e.g., Studiengesellschaft Kohle, G.m.b.H. v. Dart Indus., Inc., 726 F.2d 724, 726-27 (Fed. Cir. 1984). The absence of any element of the claim from the cited reference negates anticipation. See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715 (Fed. Cir. 1984). Anticipation is not shown even if the differences between the claims and the prior art reference are insubstantial and the missing elements could be supplied by the knowledge of one skilled in the art. See, e.g., Structural Rubber Prods., 749 F.2d at 716-17.

In response to the arguments submitted with the amendment filed December 11, 2003, the Examiner notes that Mizuno teaches in the paragraph bridging columns 4 and 5 "a surgical section which is connected to the distal end of the insertion section which is able to bend to treat an affected part of the subject and/or provide image of the affected part". The Examiner also refers to element 309 of Figure 38, disclosed as a "bending tube", and notes that Mizuno mentions that the endoscopes are inserted using a manipulator. Based on these disclosures of Mizuno, the Examiner summarily concludes that the endoscope of Mizuno is inserted through a flexible conduit (the manipulator). Applicant respectfully disagrees.

The noted passages of Mizuno do not refer to a flexible conduit within which the endoscope 301 is passed but rather refer to axially connected segments of the endoscope or other "surgical means" Mizuno advances. Element 309, referenced by the Examiner in Figure 38 is simply a portion of the elongated endoscope as understood from Figure 37A. Moreover, there is no description or teaching in Mizuno that the "manipulator" he mentions is a flexible conduit. Rather, if anything the manipulator would be understood to be a manipulator mechanism, e.g., incorporated in the

endoscope, to bend the end of the endoscope, e.g., via bend section (309) to allow the endoscope to navigate around turns and bends approaching its target. Nothing in Mizuno would suggest that the "manipulator" is a flexible tube. Thus, it is respectfully submitted that Mizuno does not teach a flexible conduit through which the endoscope is advanced.

With respect to applicant's arguments that the anchoring in Mizuno occurs prior to incision, the Examiner argues that the claim does not limit the order in which the recited methodical steps occur. While claim 1 does not *per se* limit the method of the invention to the recited steps in the recited order, at least some of the steps recited must necessarily follow (or precede) other executed steps by the language thereof. Importantly in this regard, claim 1 includes the step "advancing a distal end of said flexible conduit so that distal end of said conduit extends through said wall" (Emphasis added). As noted above, Mizuno does not disclose an elongated flexible conduit through which an endoscope is advanced, but even if Mizuno is considered to disclose a conduit through which an endoscope is advanced to the target tissue 323, Mizuno does not teach advancing a distal end of a flexible conduit through the target wall segment. In fact, as emphasized previously, neither surgical manipulator 302 nor endoscope 301 is advanced through wall 322. Rather, Mizuno expressly teaches in the 4<sup>th</sup> paragraph of column 27 that the diseased tissue 323 is clamped between the surgical manipulator 302 and the endoscope 301 and then the diseased tissue is either irradiated or excised. There is no passage of a flexible conduit, through which the endoscope is received, through wall 322 in Mizuno.

Claim 1 also requires that the distal end of the flexible conduit be anchored with respect to the wall. The only anchoring taught in Mizuno is of surgical manipulator 302 and endoscope 301. There is no passage of a flexible conduit through a wall and there is no anchoring of a flexible conduit (through which the endoscope is received) to the wall. It is further respectfully submitted that it would be unobvious in Mizuno to advance his endoscope or any other structure through wall 322 as the only incision or

cutting mentioned in connection with this embodiment of Mizuno is the excising of diseased tissue 323. As such, there would be no purpose to advancing the endoscope or any other structure, other than a knife, through wall 322.

Claim 1 also includes the step of "withdrawing said conduit and said endoscope through said wall", again necessarily both the conduit and the endoscope have previously been advanced through the wall in order to be withdrawn as claimed.

Mizuno does not meet any of the foregoing limitations of claim 1 so that it cannot properly be said that the invention is anticipated by Mizuno.

It is further respectfully submitted that the invention is not obvious from Mizuno either. In this respect, without the benefit of applicant's disclosure, Mizuno teaches only isolating and treating a diseased wall segment 323 between a surgical manipulator 302 and an endoscope 301. Mizuno does not teach or in any way suggest the concept of accessing, e.g., the peritoneal cavity, by advancing a flexible conduit through a natural orifice, incising a wall of the digestive tract, advancing the flexible conduit through that wall and anchoring it to it, and advancing an endoscope through the flexible conduit into the cavity. This approach to surgical intervention in the peritoneal cavity was previously unknown in the art. In this regard, the Examiner's attention is respectfully directed to the attached meeting review report "Best of DDW 2002", page 133, middle column, which briefly discusses what is characterized as a "very provocative presentation on endoscopic gastrojejunostomy" which is characterized as introducing "the concept of entering the peritoneal cavity from the stomach". Reference 23 identified in that section can be seen from page 140 to be an abstract of the inventors, a copy of which is also attached for the Examiner's information and reference. Moreover, attached for the Examiner's information and reference, is an article in press (not yet published) of the inventors, which has been recently accepted for publication in the "New Methods & Materials" section of Gastrointestinal Endoscopy. Clearly, then, those skilled in the art have also recognized and understood that the

method proposed by the inventors is a new and novel approach to endoscopic procedures. In view of the foregoing, reconsideration and withdrawal of the Examiner's rejection is respectfully requested.

Claims 1 and 3 were rejected under 35 USC 103(a) as unpatentable over Mizuno in combination with Inoue. Applicant respectfully traverses this rejection.

In response to the arguments presented with the December 11, 2003 response, the Examiner asserts that it is "well known in the art" that "the full peripheral extent of the lesion is not visible from the surface being treated. Thus dilating, insufflating, and inspecting the outer wall of the organ...is not merely obvious, but a necessity". Even if dilating, insufflating and inspecting the outer wall of the organ is a necessity, which applicant does not concede as a general rule, applicant's claims are more specific in this respect than the Examiner's interpretation and characterization in the arguments of the April 28, 2004 Official Action. In this regard, claim 3 specifically provides that after forming the incision (in the target wall segment) and before the claimed advancing the flexible conduit (through the wall), the incision is dilating to facilitate passage of the conduit. The Examiner's stated concerns relating to the extent of a lesion are irrelevant to the concept of dilating an incision for the passage of a conduit. In case of claim 3, it is made clear that the incision step precedes the step of advancing the conduit through the wall and provides that the incision in the target wall segment is dilated to facilitate the conduit passage. In Mizuno, the only incision in the target wall segment is to excise the lesion. As such, there is no conceivable reason to dilate the incision. Thus, claims 1 and 3 are patentable over Mizuno and Inoue.

Claims 1, 4 and 5 were rejected under 35 USC 103(a) as unpatentable over Mizuno et al in combination with Vander Salm et al. Applicant respectfully traverses this rejection.

With respect to claim 5, claim 5 specifically requires that the insufflation step occur after the anchoring step. The Examiner's suggestion that insufflation and

inspection is "obvious" does not address the specific limitations set forth in applicant's claim, e.g., that the claimed insufflation is after anchoring the flexible conduit. Thus, this claim is also submitted to be allowable over the prior art of record.

Claims 1 and 6 were rejected under 35 USC 103(a) as unpatentable over Mizuno et al in combination with Shermeta. Applicant respectfully traverses this rejection.

As noted above, Mizuno does not teach or suggest the concept of inserting a flexible conduit through a wall of the digestive tract and the only anchoring taught in Mizuno in respect of the embodiment of Figures 37A-38 is by virtue of the clamping of the wall 322 between manipulator 302 and endoscope 301. The fact that the balloon anchors *per se* have been provided or used in isolated circumstances in the past does not *ipso facto* mean that it would be obvious to provide a balloon anchor in the method of Mizuno or that the Mizuno assembly as so modified would meet the limitations of applicant's claim.

Section 103 does not allow the Examiner to engage in picking and choosing from the prior art only to the extent that it will support a holding of obviousness, while excluding parts of the prior art essential to the full appreciation of what the prior art suggests to one of ordinary skill in the art. In re Wesslau, 147 USPQ 391 (CCPA 1975).

As the CAFC has said, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. ACS Hospital Systems v Montefiore Hospital, 221 USPQ 929, 933 (Fed. Cir. 1984). There must be a suggestion in the art relied upon to use what one reference discloses in or in combination with the disclosure of the other reference or references relied upon by the Examiner. In re Grabiak, 226 USPQ 870, 872 (Fed. Cir. 1986).

Use of a dual balloon fixation method would be inconsistent with the Mizuno procedure as the Shermeta balloon anchor is used for a tube that passes through a wall

and in fact precludes access to the region around the incision. In contrast, Mizuno does not propose to advance any instrument or conduit through a wall but rather isolates a wall segment by clamping it between a manipulator and an endoscope. The skilled artisan would see no use or advantage to a balloon anchor in a procedure of the type taught by Mizuno. Therefore, the proposed modification of the Mizuno procedure is not one that would be made by the skilled artisan in the absence of applicant's disclosure.

Claims 1 and 7-18 were rejected under 35 USC 103(a) as unpatentable over Mizuno et al in combination with Wilson-Cook Brochure, and claim 19 was rejected as unpatentable over Mizuno in combination with Wilson-Cook and further in view of Bard Brochure. Applicant respectfully traverses these rejections.

With regard to the Examiner's continuing rejection of claims 7-19, the Examiner has summarily dismissed applicant's arguments because they are "predicated on presumed deficiencies of Mizuno". Applicant respectfully submits, however, that with respect to *inter alia* claim 19, applicant has presented very specific arguments challenging the propriety of the Examiner's proposed modification of Mizuno and Wilson-Cooke in view of the Bard Brochure. More particularly, applicant has noted that in Mizuno, a diseased wall segment 323 is isolated by being clamped between an endoscope and a manipulator and then the diseased tissue is removed. As such, the diseased tissue would be cut away and there would be no use or advantage whatsoever to a dilating balloon. On the contrary, once the diseased tissue 323 is removed, the surgeon would wish to close the incision, not dilate it. Thus, Mizuno teaches no use whatsoever for a dilating balloon and the Bard Brochure does not teach or suggest a use for a dilating balloon in the procedure of the type taught by Mizuno's Figures 37A and B. Only applicant teaches the advantageous use of a dilating balloon following an incision by a needle knife, i.e., to allow insertion through the incised wall of a flexible conduit, so that an endoscope can thereafter be advanced into the thus accessed cavity.

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It is respectfully submitted that the Examiner has offered no arguments to rebut the arguments presented to challenge the Examiner's conclusion of obvious with respect to claim 19.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and an early Notice to that effect is earnestly solicited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By:



Michelle N. Lester  
Reg. No. 32,331

MNL:slj  
1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100